DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

May 10, 2001

Herbert Needman
Administrator and CEO
Temple Community Hospital
235 North Hoover Street
Los Angeles, CA 90004

W/L Number: 44 - 01
Inspection ID: 1914290006
CFN: 20-30,185
FEI: 1000519346

Dear Mr. Needman:

We are writing to you because on February 20, 2001, your facility was inspected by a representative of the State of California acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

- Level 1: Phantom quality control (QC) records were missing for eight (8) weeks (weeks of January 17, January 24, February 1, February 7, February 14, February 21, February 28, and November 6 of the year 2000) for unit #2 (a [redacted] machine, model [redacted]) located in the mammography room.

- Level 1: Processor QC records were missing 10 out of 10 days of operation on February 1, 7, 11, 16-17, 22-25, and 28 of the year 2000. Processor QC records were missing 100% for processor #2 (a [redacted] machine, model [redacted]) located in the radiology darkroom.

- Level 1: Processor QC records were missing for ten (10) consecutive days for processor #2 (a [redacted] machine, model [redacted]) located in the radiology darkroom.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- Level 2: 2 of 10 random reports reviewed did not contain an assessment category.

- Level 2: There was no designated audit (reviewing) interpreting physician.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations; and

- sample please provide records that demonstrate proper record keeping procedures if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

re: Temple Community Hospital
re: Warning Letter Number 44 - 01

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas (MQSA Auditor) at telephone number (949) 798-7708.

Sincerely,

Alonza E. Cruse
District Director

cc:

County of Los Angeles
Department of Health Services
Radiation Management
550 South Vermont Avenue; Room #600
Los Angeles, CA 90020

State of California
Dept. of Health Services - Radiological Health Unit
550 South Vermont Avenue; Suite #601
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